

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

16

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/011,167 10/05/98 GEUZE

J RILE.001.000

HM12/0814

EXAMINER

BARBARA RAE VENTER  
RAE VENTER LAW GROUP  
PO BOX 60039  
PALO ALTO CA 94306-0039

DECLLOUX, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

13

DATE MAILED:

08/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

|                              |                               |                                  |
|------------------------------|-------------------------------|----------------------------------|
| <b>Office Action Summary</b> | Application No.<br>09/011,167 | Applicant(s)<br>Gueze And Mellef |
|                              | Examiner<br>DeCloux, Amy      | Group Art Unit<br>1644           |

Responsive to communication(s) filed on mailed 6/27/00

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 2-4, 6, and 9-13 is/are pending in the application.

Of the above, claim(s) 9-12 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 2-4, 6, and 13 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

**DETAILED ACTION**

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Amy DeCloux, Art Unit 1644.
2. Applicant's amendment, mailed 6-27-2000 (Paper No. 12), is acknowledged.
3. Applicant's election with traverse of Group I, Claims 1-4, 6 and 13, and species A, antigen presenting vesicles comprising MHC Class I molecules, in Paper No. 12, mailed 6-27-2000, is acknowledged. It is noted that Claim 1 has been canceled in the preliminary amendment. The traversal is on the ground(s) that the special technical features of Group I and Group II directed to an antigen presenting vesicle and a method of obtaining an antigen presenting vesicle, define a contribution over the Melief '160 patent because '160 does not teach, suggest or mention anything about MHC enriched exosomes or any other kind of vesicle obtainable from a cell. This is not found persuasive because as applicant has pointed out, the '160 patent extends its invention to all antigen presenting lipid bilayers carrying vehicles incorporating empty MHC molecules that can be loaded with exogenous peptide. Since the term "vehicle" instead of cells, the '160 patent is clearly not limited to cells. Therefore, a technical feature does not define a contribution over the prior art.

With regard to the traversal of the species requirement, applicant argues that vesicles enriched with either MHC Class II or Class I are highly related and few in number to avoid imposing an undue search burden on the examiner. However it is well known that Class I and Class II antigens are processed and presented in two separate compartments and pathways, and therefore such a search would constitute an undue search burden.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 9-12 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
5. Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.
6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7. The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 C.F.R. §§ 1.97-1.99.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (i) Abstract of the Disclosure.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2-4, 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There is insufficient guidance in the instant specification and in the prior art for an antigen presenting vesicle free from its natural surroundings obtainable from an antigen presenting cell comprising a membrane and an MHC Class I protein or fragment thereof, as recited in claim 13, and its dependent claims 2-4 and 6, though the specification, is enabling for an antigen presenting vesicle free from its natural surroundings obtainable from an antigen presenting cell comprising a membrane and an MHC class II protein or fragment thereof. As evidenced by Figure 1 in Delves et al., (Molecular Medicine Today, 3(2):55-60, 1997), it is well known in the art that MHC Class I and Class II antigen presentation follow distinct,

compartmentalized pathways, and that Class II bind antigens in endosomes or specialized loading compartments that are distinct from Class I molecules. Therefore, it is not clear from the instant specification that it is possible to isolate exosomes comprising class I (as opposed to class II) molecules from the supernatant of antigen presenting cells as taught by the specification.

Based upon the paucity of information contained within the instant specification in this regard, it would require an undue amount of experimentation on the part of one skilled in the art to use the claimed polypeptide for the asserted utilities.

In view of the quantity of experimentation necessary to use the claimed invention, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, it would require an undue amount of experimentation on the part of one skilled in the art to use the claimed methods for the asserted utilities, and this is not sanctioned by the statute.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

11. Claims 13, 2, 3, 4 and 6 are rejected under 35 U.S.C. § 102(e) as being anticipated by Meleif et al. (U.S. Patent No. 5,731,160, 1998).

Melief et al. teach an antigen specific bilayer carrying vesicles from artificial lipid bilayer systems, as well as cells such as antigen presenting cell lines RMA-S, said vesicles incorporating MHC molecules that can be loaded with exogenous peptides (see entire article, including column 5, lines 47-63 and 20-26). Therefore, the referenced teachings anticipate the claimed references.

12. Claims 13, 2, 3, 4 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Walden et al. (Nature, 315:327-329, 1985). (c1 IDS)

Walden et al. teach liposomes carrying a foreign protein antigen and MHC Class II molecules from membrane bound spleen cells which contain antigen presenting cells, and also that foreign antigens were attached to the lipid membranes that were capable of stimulating T cells in an antigen specific manner (see entire article especially page 327, column 2, last 2 paragraphs). Therefore, the referenced teachings anticipate the claimed references.

13. Claims 13, 2, 3, 4 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Harding and Gueze (J. Immunology, 151:3988-3998, 1993). (c2 IDS)

Harding and Gueze teach the subcellular fractionation of murine peritoneal macrophages to produce fractions containing MHC Class II molecules (see entire article, especially page 3990, column 2, last 2 paragraphs), and that fractions containing lysozymes and light density membranes contained peptide-MHC-II complexes that were detected by T cells, (see entire article especially page 3992, column 1, last paragraph). Therefore, the referenced teachings anticipate the claimed references. The open language of "comprising" is noted in claim 13.

14. Claims 13, 2, 3, 4 and 6 are rejected under 35 U.S.C. § 102(b) as being anticipated by Amigorena et al (Nature, 369:113-120, 1994). (c3 IDS)

Amigorena et al teach the subcellular fractionation of a B cell line to produce fractions containing membrane vesicles with MHC Class II molecules (see entire article, especially page 114, column 2, last paragraph), which contained processed peptide (see entire article, especially page 118, first paragraph of the Discussion Section). Therefore, the referenced teachings anticipate the claimed references. The open language of "comprising" is noted in claim 13.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the

examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640, Technology Center 1600  
August 11, 2000

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 / 644